

K030457

**Section II - Section 510(k) Premarket Notification Summary  
(as required by 807.92 (j))**

APR 08 2003

**Submitter:**

PointDx, Inc.  
635 West Fourth Street, Suite 200  
Winston-Salem, NC 27101  
Phone: 336.723.1450  
Fax: 336.723.1458

**Date Prepared:**

February 7, 2003

**Contact Person(s):**

Robert Anderson, Chief Operating Officer  
Francis Bonk, Director of Quality Assurance and Regulatory Affairs  
336-723-1450 (v)  
336-723-1458 (f)

**Device Trade Name:**

REX™

**Device Common Name:**

PACS / Image Processing Software

**Classification Name:**

Class II – System, Image Processing, RA (90) LLZ

**Substantially Equivalent To:**

REX™ 1.0	Rapidia® V 2.0
(K021099)	(K012290)
PointDx, Inc.	3D Med Co, Ltd.
635 West Fourth Street	940-319 Research Park
Suite 200	SNU, San 4-8
Winston-Salem, NC 27101	Bongcheon-dong, Gwanak-gu
USA	Seoul 151-818
	Republic of Korea

**Device Description:**

REX™ 3.0 is a tool for 3D (three dimensional) and 2D (two dimensional) viewing and manipulation of DICOM compliant CT and MR images. The proposed software provides real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.

**Indications for Use:**

REX™ 3.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT and MR scanners. REX™ 3.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.

**Technological Comparison to Predicate Device:**

The proposed and predicate devices are both software programs that can be used for manipulation of DICOM-compliant CT and MR images. The proposed and predicate software can be operated from a personal computer. REX™ 3.0 adds the capability to display MR images to REX™ 1.0 and

convenience of using two monitors, one for image viewing, and the other for report viewing. The REX™ 3.0 software has substantially equivalent features and specifications versus the existing REX™ 1.0 and Rapidia® V 2.0, for those features and specifications the two devices have in common.

**Non-Clinical Performance Data:**

The proposed REX™ 3.0 software conforms to DICOM (Digital Imaging and Communications in Medicine) Version 3.0. Validation testing confirms that REX™ 3.0 performs all input functions, output functions, and all required actions according to the functional requirements specified in the Software Requirements Specification.

To ensure performance to specifications, Federal Regulations and user requirements:

- Software Development Practices and
- The Validation and Verification Process

have been followed. Procedures specify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation and maintenance.

**Adverse Effects on Health:**

The potential hazards are identified in the Hazard Analysis and are controlled by:

- Designing controls directed at the cause and/or
- Introducing protective measures and/or
- Warning the Users.

**Conclusions:**

REX™ 3.0 does not result in any new potential safety risks and performs in accordance with its intended use as well as REX™ 1.0 and Rapidia® V 2.0 devices currently on the market. PointDx considers features of REX™ 3.0 to be substantially equivalent to REX™ 1.0 (K021099) with the addition of MR image analysis functions and a subset of features in common with the Rapidia® V 2.0 (K012290) device.

## Substantial Equivalence Chart

Tabular Comparison of Features and Specifications of REX™ 3.0, REX™ 1.0 and Rapidia® V2.0

System	REX™	REX™	Rapidia®
<b>Version</b>	<b>3.0</b>	<b>1.0</b>	<b>2.0</b>
<b>Manufacturer</b>	PointDx, Inc.	PointDx, Inc.	3D Med Co., Ltd.
<b>510(k) Number</b>	-	(K021099)	K012290
<b>Classification</b>	Class II 892.2050 90 LLZ	Class II 892.2050 90 LLZ	Class II 892.2050 90 LLZ
<b>Intended Use</b>	REX™ 3.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT and MR scanners. REX™ 3.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.	REX™ 1.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT scanners. REX™ 1.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.	Rapidia® is a software package intended for viewing and manipulating DICOM-compliant medical images from CT and MR scanners. Rapidia® can be used for real-time viewing, image manipulation, segmentation, 3D volume and surface rendering, virtual endoscopy, and issuing reports.
<b>Graphical User Interface</b>	Yes	Yes	Yes
<b>Platform</b>			
<b>PC</b>	Yes	Yes	Yes
<b>Operating System</b>			
<b>Windows 2000</b>	Yes	Yes	Yes
<b>Windows XP</b>	No	No	Yes
<b>Windows NT</b>	No	No	Yes
<b>Image Display Monitor</b>	1	1	1
<b>Report Display Monitor</b>	1	1	Unspecified
<b>Patient Demographics</b>	Yes	Yes	Yes
<b>Networking</b>			
<b>TCP/IP</b>	Yes	Yes	Yes
<b>Image Communication</b>			
<b>DICOM 3.0 compliant</b>	Yes	Yes	Yes
<b>Image Compression</b>			
<b>PNG (Lossless)</b>	Yes	Yes	Unspecified
<b>Image Processing</b>			
<b>Annotations – marker</b>	Yes	Yes	Yes

System	REXTM	REXTM	Rapidia®
<b>3D Image Processing</b>			
<b>Volume rendering</b>	Yes	Yes	Yes
<b>Image Review</b>			
<b>Still</b>	Yes	Yes	Yes
<b>Window</b>	Yes	Yes	Yes
<b>Level</b>	Yes	Yes	Yes
<b>Zoom</b>	Yes	Yes	Yes
<b>Pan</b>	Yes	Yes	Yes
<b>Flip</b>	Yes	Yes	Yes
<b>2D Measurements</b>			
<b>Length</b>	Yes	Yes	Yes
<b>Area</b>	Yes	Yes	Yes
<b>Image Source</b>			
<b>CT</b>	Yes	Yes	Yes
<b>MR</b>	Yes	No	Yes
<b>Image Input</b>			
<b>DICOM 3.0</b>	Yes	Yes	Yes
<b>Image Output</b>	PNG (lossless snapshots)	PNG (lossless snapshots)	JPEG, BMP, DICOM
<b>Use Standard Monitor</b>	Yes	Yes	Yes
<b>Patient and Study Browser</b>	Yes	Yes	Yes
<b>Multi Planer Reformatting</b>	Yes	No	Yes
<b>Measure Image Intensity Values</b>			
<b>ROI</b>	Yes	Yes	Yes
<b>Type of Software</b>			
<b>Standalone</b>	Yes	Yes	Yes
<b>Virtual Endoscopy</b>			
<b>Instant access to lesions by single click</b>	Yes	Yes	Yes
<b>Real time display of endoscopic view</b>	Yes	Yes	Yes
<b>Internal and external viewing of any hollow structures</b>	Yes	Yes	Yes
<b>Fly-through</b>	No	No	Yes
<b>Real time interactive correlation among 3D image, endoscopic image and MPR images with respect to the point of view, viewing area and lesion localization</b>	No	No	Yes

System	REX™	REX™	Rapidia®
Display multiple objects in different color and opacity	No	No	Yes
Local Image Storage	Yes	Yes	Yes
True Color	Yes	Yes	Yes
User Login	Yes	Yes	Unspecified
Preset Window and Level	Yes	Yes	Yes
Image Conversion	Yes (for viewing in browser)	Yes (for viewing in browser)	Yes
Device Users Trained Physicians	Yes	Yes	Yes
Compliance Standards DICOM 3.0	Yes	Yes	Yes
Algorithms Volume Rendering	Yes	Yes	Yes
Reporting	Yes	Yes	Yes
Physical Characteristics	<ul style="list-style-type: none"> <li>• Software Package</li> <li>• Operates on off-the-shelf hardware (multiple vendors)</li> <li>• Windows 2000 operating system</li> <li>• DICOM compatible</li> </ul>	<ul style="list-style-type: none"> <li>• Software Package</li> <li>• Operates on off-the-shelf hardware (multiple vendors)</li> <li>• Windows 2000 operating system</li> <li>• DICOM compatible</li> </ul>	<ul style="list-style-type: none"> <li>• Software Package</li> <li>• Operates on off-the-shelf hardware (multiple vendors)</li> <li>• Windows 2000, XP, or NT operating system</li> <li>• DICOM compatible</li> </ul>
Safety	<ul style="list-style-type: none"> <li>• Clinician interactive review/editing of data integral to use of tool</li> </ul>	<ul style="list-style-type: none"> <li>• Clinician interactive review/editing of data integral to use of tool</li> </ul>	<ul style="list-style-type: none"> <li>• Unspecified</li> </ul>

**Table 1. Substantial Equivalence**



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 08 2003

Mr. Francis Bonk  
Director of Quality Assurance  
and Regulatory Affairs  
PointDx, Inc.  
635 West Fourth St., Suite 200  
WINSTON-SALEM NC 27101

Re: K030457  
Trade/Device Name: REX™ 3.0 PACS / Image  
Processing Software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: February 7, 2003  
Received: February 11, 2003

Dear Mr. Bonk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

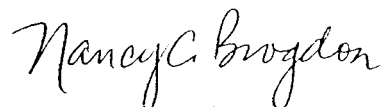
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 8 3 0457

Device Name: REX™ 3.0 PACS / Image Processing Software

**INDICATIONS FOR USE:**

Intended Use:

***Indications for Use:***

REX™ 3.0 is a software package intended for viewing and manipulating DICOM-compliant medical images acquired from CT and MR scanners. REX™ 3.0 can be used for real-time image viewing, image manipulation, 3D volume rendering, virtual endoscopy, and issuance of reports.

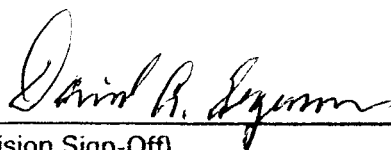
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X    
Per 21 CFR 801.109

OR

Over-The-Counter Use) \_\_\_\_\_



(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number

K030457